

Exhibit B



Deposition of:
Mark Eisenberg , M.D.

July 6, 2017

In the Matter of:
**In Re: Bard IVC Filters Products
Liability**

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1 image the body. So I do a lot of the things that
2 radiologists do, but I am not a radiologist.

3 Q. You don't hold yourself out as a
4 radiologist; right?

5 A. No, I do not.

6 Q. Now, you understand that IVC, the
7 acronym stands for inferior vena cava; right?

8 A. Yes.

9 Q. And if we refer in this deposition
10 to IVC or IVC filter you will understand what I
11 am talking about?

12 A. Yes, I will.

13 Q. And I recall from your last
14 deposition you have never inserted an IVC filter;
15 right?

16 A. No, I have not.

17 Q. You have never removed an IVC
18 filter?

19 A. No.

20 Q. Have you ever been present in a room
21 when an IVC filter was inserted?

22 A. I have not been present in a room
23 when an IVC filter was inserted, but I have put
24 in central lines into the inferior vena cava for
25 my own procedures, and then immediately after my

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1 procedure the patient moved to a radiology suite
2 where the same line that I had left in place was
3 used for insertion of the filter.

4 Q. You have never been in an operating
5 room at the moment when an IVC filter was
6 implanted in a patient; right?

7 A. No, that's correct.

8 Q. You have never been in an operating
9 room at the moment when an IVC filter was removed
10 from a patient; right?

11 A. Correct.

12 Q. You have never had a patient, to
13 your knowledge, who experienced an adverse event
14 from having an IVC filter in them; right?

15 A. Not to my knowledge, no.

16 Q. You know that there are doctors and
17 scientists who routinely publish in the world's
18 literature about issues related to IVC filters?

19 A. I do.

20 Q. You have never published anything
21 about IVC filters?

22 MR. ROTMAN: Objection.

23 THE WITNESS: That's correct. I
24 would like to elaborate on that a little bit,
25 which is through the course of this case I have

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1 filters; correct?

2 A. That's correct.

3 Q. You have never received a grant to
4 do research on IVC filters; right?

5 A. Right.

6 Q. Of course, as we have -- strike
7 that. You are well aware that there are doctors
8 who specialize in the implantation and removal of
9 IVC filters; right?

10 A. Yes.

11 Q. You are not a doctor who specializes
12 in the implantation or removal of IVC filters;
13 right?

14 A. No, I do not.

15 Q. You don't hold yourself out among
16 your peers as an expert in IVC filters, do you?

17 A. No, I do not.

18 Q. Now, prior to your retention for the
19 Plaintiffs in this litigation, you had never done
20 any research on IVC filters; right?

21 A. I read some papers on IVC filters,
22 but I had never done any research on them.

23 Q. Prior to your retention as a
24 litigation expert for Plaintiffs, you had never
25 done any organized or concerted research on IVC

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1 question earlier on that you don't understand, I
2 will rephrase it, it's not because you don't
3 understand. It's because I have asked a terrible
4 question. That was one of them. Thanks for the
5 clarification. Let me go back, with that
6 understanding.

7 A. Okay.

8 Q. You don't hold yourself out as an
9 expert or specialist in the detection of
10 fractures associated with IVC filters, do you?

11 A. No, I do not.

12 Q. You don't hold yourself out as an
13 expert in the potential migration of IVC filters;
14 right?

15 A. I would like to go back to the
16 previous question. You are right. I don't hold
17 myself out as a specialist in the detection of
18 fractures and migrations but, to the extent that
19 they, for example, might migrate to the heart and
20 cause symptoms, I potentially could be involved
21 in that.

22 Q. Do you hold yourself out as an
23 expert in the detection of tilt in a patient with
24 an IVC filter?

25 A. No, I do not.

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1 Q. Do you hold yourself out as an
2 expert in the detection of perforation associated
3 with an IVC filter?

4 A. No. Again, I don't hold myself out
5 as an expert in the area, but if a patient became
6 symptomatic I could potentially be involved.

7 Q. You understand that a significant
8 portion of patients with alleged adverse events
9 associated with IVC filters are indeed
10 asymptomatic; right?

11 MR. ROTMAN: Can I have the question
12 re-read, please?

13 QUESTION WAS READ BACK.

14 MR. ROTMAN: Objection.

15 THE WITNESS: I know that some
16 patients that have complications related to IVC
17 filters are asymptomatic. I know that there is
18 many others who are symptomatic and that have had
19 major complications related to them. I would
20 also say to that point that the patients who
21 received IVC filters, many of them have many
22 comorbidities and ultimately die not long after
23 they get the IVC filters, and it may be a death
24 that's related to the IVC filter but there is no
25 way to know because there is no autopsy results.

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1 related to the percentage of individuals who have
2 died as a result of alleged adverse events from
3 IVC filters; true?

4 A. That's true.

5 Q. Can you recall a specific patient
6 that you have ever had for whom you have
7 prescribed an IVC filter?

8 A. I have not personally prescribed an
9 IVC filter for an individual patient. I have
10 certainly been involved in the diagnosis of deep
11 vein thrombosis, pulmonary emboli, starting
12 anti-coagulation in these patients, and some of
13 these patient do go on to receive IVC filters but
14 I am typically not the one who makes the
15 determination that they got that.

16 Q. You personally have never prescribed
17 an IVC filter for a patient; right?

18 A. That's correct.

19 Q. You have been involved in the care
20 of patients who have deep vein thrombosis,
21 though?

22 A. Yes.

23 Q. You don't hold yourself out among
24 your peers as an expert in the specific reasons
25 why an IVC filter might fracture; right?

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1 literature and other materials in connection with
2 your work as a litigation expert in this case;
3 right?

4 A. Yes.

5 Q. Outside of your work as a litigation
6 expert, you don't hold yourself out as an expert
7 in the reasons why an IVC filter may fracture;
8 right?

9 A. Correct.

10 Q. Or migrate?

11 A. Correct.

12 Q. Or tilt?

13 A. Correct.

14 Q. Or perforate?

15 A. Yes.

16 Q. Or embolize?

17 A. Yes.

18 Q. Does the rate of a potential IVC
19 filter complication vary depending on the reasons
20 why a patient receives an IVC filter?

21 A. Can you repeat the question, please?

22 Q. Sure. Strike that question. You
23 are not an expert in any way, shape, or form in
24 bench testing for medical devices?

25 A. No, I don't do any bench testing or

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1 hold myself out as an expert in bench testing.

2 Q. Do you consider yourself an expert
3 in animal testing for medical devices?

4 A. No. Again, I don't do any animal
5 testing and I don't hold myself out as an expert
6 in any kind of animal testing.

7 Q. You are not an engineer; right?

8 A. I am not an engineer.

9 Q. You are not a materials engineer;
10 right?

11 A. I am not a materials engineer
12 although again, I have read this extensive
13 literature about IVC filters, so I would say I
14 know more about it than the average physician.

15 Q. You are not a materials engineer;
16 right?

17 A. No, I am not.

18 Q. You are not a mechanical engineer?

19 A. No.

20 Q. You are not an expert in IVC filter
21 design?

22 A. No, I am not an expert in IVC filter
23 design, but again I have more knowledge than the
24 average person about it, after reading all this
25 literature.

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1 Q. You are not an expert in IVC filter
2 design?

3 A. Correct.

4 Q. Can you distinguish one IVC filter
5 from another based on visual observation alone?

6 A. I think I can. Certainly in the
7 Bard series I am pretty familiar. Not with every
8 single variation in design from -- you know, from
9 design change to design change, but.

10 Q. We are going to get back on to areas
11 we have covered before. I just want to make sure
12 we are clear on this transcript on a couple of
13 different points. You have been crystal clear in
14 the past you don't hold yourself as an FDA
15 regulatory expert.

16 A. Correct.

17 Q. That stands true today?

18 A. No, I am not.

19 Q. You are not an expert on what a
20 device manufacturer is required to do by law or
21 regulation to bring a device to market?

22 A. No, I am not an expert in that area.

23 Q. You are not an expert in what a
24 device manufacturer is required to do in order to
25 be compliant with pharmacovigilance requirements;

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1 right?

2 A. No, I can't hold myself out as an
3 expert in FDA requirements.

4 Q. You don't consider yourself an
5 expert in what a device manufacturer is required
6 to do by law in order to comply with various
7 reporting requirements; right?

8 A. No. That's correct.

9 Q. You are not an expert in what a
10 device manufacturer is required to do by law or
11 regulation to update doctors about risks
12 associated with its products; right?

13 A. No, I would say that I am not an
14 expert in what's legally required, although I
15 know as a physician myself that -- what I would
16 expect a company to inform physicians about their
17 devices.

18 Q. You don't consider yourself an
19 expert in what a device manufacturer is required
20 to do by law or regulation to update doctors
21 about risks associated with products?

22 A. That's correct. I am not an expert
23 in that area.

24 Q. Have you ever taught a class on the
25 subject of pharmacovigilance?

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1 A. Well, I don't think I have formally
2 taught a course on pharmacovigilance. Although I
3 don't hold myself out as an expert in
4 pharmacovigilance, many of the research studies I
5 have done have involved, you know, safety and
6 certainly efficacy studies of different devices
7 and drugs, so I have a fair amount of knowledge
8 on pharmacovigilance. I don't think I have
9 formally taught a course on that topic.

10 Q. Let me break that down a little bit,
11 and you let me know if I get this wrong; okay?
12 Some of the research you have done in the past
13 touches on issues of product safety; right?

14 A. Yes.

15 Q. You don't hold yourself out as an
16 expert in pharmacovigilance; right?

17 A. Again, I would say it's one of the
18 areas that I have some knowledge in, but do I
19 hold myself out as an expert in that area?
20 Probably not.

21 Q. You are not an expert in corporate
22 ethics; right?

23 A. No.

24 Q. You are not an expert in responsible
25 corporate conduct; right?

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1 A. That's correct.

2 Q. You have never worked for FDA;
3 right?

4 A. No, I have not. Although I
5 mentioned in the Austin deposition that one of my
6 clinical trials, the FDA contacted me for some
7 additional information, but I was not compensated
8 and certainly can't construe myself as working
9 for them.

10 Q. You are not an expert in medical
11 device labelling; right?

12 A. No, I am not.

13 Q. And you have never drafted a label
14 for a medical device?

15 A. No, I have never drafted a label for
16 a medical device.

17 Q. You have never advised a medical
18 device company related to product labelling?

19 A. No, I don't believe so.

20 Q. The FDA has never consulted you
21 about the appropriate labelling for a medical
22 device; right?

23 A. No, they have not.

24 Q. You have never been consulted by a
25 device manufacturer with respect to appropriate

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1 labelling for a medical device; right?

2 A. Correct.

3 Q. You have got no expertise in
4 marketing of medical devices or drugs; right?

5 A. Well, I don't have -- I would call
6 it professional expertise. I have certainly been
7 a member of some advisory boards for some drug
8 companies that -- so we had meetings that were
9 related to marketing of particular drugs. So --
10 I certainly don't hold myself out as an expert in
11 those areas, but I have some experience of
12 marketing for some pharmaceuticals.

13 Q. What are you referring to?

14 A. As an example, there is a drug,
15 varenicline, which is a smoking cessation drug.
16 So Pfizer has advisory boards for physicians that
17 do research in that area, and we might meet once
18 every year or two, and they would present new
19 data that's come out, and get our take on that
20 and say: How does that impact on -- or how
21 should we present this to physicians in our
22 marketing effort.

23 Q. You don't consider yourself an
24 expert in what a pharmaceutical or medical device
25 company is allowed to do in terms of

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1 communication with physicians about their
2 products; right?

3 A. No.

4 Q. Have you ever worked in any capacity
5 for Bard?

6 A. No.

7 Q. So I want to do a little bit of
8 additional housekeeping. I think that you have
9 got your expert reports with you and they have
10 some of your notes on them; right?

11 A. Yes.

12 Q. You can feel free to refer to those
13 throughout the course of today's deposition. I
14 have my own copies and I know that Steve does
15 too. I am going to take my copies out. I just
16 want to make sure that what I have is identical
17 to what you have. So I will mark for the record
18 Exhibit copies and you can feel free to use the
19 Exhibits or your own personal copy. The choice
20 is yours.

21 A. Okay.

22 MR. ROTMAN: I don't have copies.
23 You made an assumption about my having copies. I
24 don't have copies of his reports.

25 MR. BUSMAN: I have extra copies.

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1 have any articles about IVC, period; right?
2 Strike that. I messed it up. You don't have any
3 articles about IVC filters at all listed in your
4 curriculum vitae; right?

5 A. No, I believe that's right; yes.

6 Q. You don't have any articles that you
7 have ever written about the value, if any, of
8 reviewing corporate documents to analyze product
9 risks; right?

10 A. No, I do not.

11 Q. You are not an expert in reviewing
12 corporate documents; right?

13 A. I don't hold myself out as an expert
14 in that area, but I have had some experience now
15 through this litigation and others, looking at
16 corporate documents.

17 Q. You have opinions about corporate
18 documents based on your review of the corporate
19 documents, but you certainly don't hold yourself
20 out as an expert in the review of corporate
21 documents; right?

22 A. That's correct.

23 Q. Look at paragraph 12, please.

24 A. Yes.

25 Q. "My research interests include

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1 imaging procedures.

2 Q. So back to your report here. You
3 have got after paragraph 22 a heading II which
4 states: "Conclusions, Standards and Main
5 Opinions". Do you see that?

6 A. Yes, I do.

7 Q. I want to try to go over how your
8 report is organized in a general sense; okay?

9 A. Okay.

10 Q. Now, a significant portion of your
11 expert report is based on a factual narrative
12 from the corporate documents you have reviewed;
13 right?

14 A. Yes.

15 Q. You try to be as accurate as you
16 possibly can when referring to those documents;
17 right?

18 A. Yes.

19 Q. You are not paraphrasing, but you
20 are trying to quote directly in most instances;
21 right?

22 MR. ROTMAN: Objection.

23 THE WITNESS: I believe in most
24 instances I quote directly from the document, but
25 occasionally, if there is multiple documents that

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1 say the same thing, I may have paraphrased.

2 BY MR. BUSMAN:

3 Q. Now, obviously you didn't purport to
4 have reviewed every single document produced in
5 this litigation; right?

6 A. No, that's correct.

7 Q. Your understanding is that was
8 millions of pages of documents; right?

9 A. Yes.

10 Q. How did you go about -- strike that.
11 Who chose the corporate documents that you,
12 yourself, reviewed?

13 A. Well, I was provided with a Drop Box
14 of a huge number of corporate documents from
15 which I could, you know, pick and choose. My
16 attention was drawn to certain corporate
17 documents by the Lawyers as well. I would say
18 also, in my reading through this case, I have
19 also gone back to see other documents that
20 perhaps were referred to in other expert reports.

21 Q. The universe of corporate documents
22 that you were provided -- strike that. The
23 universe of corporate documents you had access to
24 were provided by the Plaintiffs' Attorneys;
25 right?

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1 A. Yes.

2 Q. Within that universe of documents
3 you were specifically directed to certain
4 documents that the Plaintiffs' Attorneys wanted
5 your opinions on; right?

6 A. In many instances, yes.

7 Q. Did you, yourself, draft this expert
8 report?

9 A. Yes, I did.

10 Q. You wrote every word of it?

11 A. Yes.

12 Q. Now, obviously your focus in this
13 case was on the specific documents that support
14 your theory of the case; right?

15 A. Repeat that.

16 Q. We established that there were
17 potentially millions of pages produced in this
18 litigation; right?

19 A. Yes.

20 Q. Your focus was on documents that
21 support your specific theory of the case; right?

22 MR. ROTMAN: Objection.

23 THE WITNESS: No, I wouldn't say
24 that. I think that I -- I looked at most of the
25 documents, not all of the documents, that the

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1 right?

2 A. I believe so.

3 Q. And those are the doctors that are
4 being set forth as what we will call subject
5 matter IVC filter experts; right?

6 A. Yes.

7 Q. And you are not holding yourself out
8 as a subject matter IVC filter expert in this
9 case, are you?

10 A. No.

11 Q. Now, in paragraph 23 --

12 A. Well, I would like to qualify that.
13 I am not holding myself out as an IVC filter
14 subject matter expert, but I am an interventional
15 cardiologist who takes care of patients with DVTs
16 and pulmonary emboli who get IVC filters. I have
17 patients in my practice who have IVC filters, so
18 I am pretty comfortable, and I am certainly
19 comfortable with the ideas of informed consent
20 for procedures and for devices. So there is a
21 lot of overlap there.

22 Q. I am going to object and move to
23 strike as non-responsive. In this case you are
24 not holding yourself out as a subject matter IVC
25 filter expert the way, for example, Drs Kinney,

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1 Roberts and Calva are?

2 A. That's correct.

3 Q. In paragraph 23 you state that your
4 expert opinions are focused primarily on the
5 reasonable expectation that physicians have of
6 medical device companies like C.R. Bard. You say
7 that in part; right?

8 A. Yes.

9 Q. Are you, in this litigation,
10 attempting to give an opinion on what other
11 doctors would think and expect or are you
12 speaking for yourself?

13 A. I think that I am pretty reflective
14 of the average physician in terms of what they
15 would expect from a device company.

16 Q. What body, organization or group has
17 given you the authority to speak for other
18 physicians in this case?

19 A. I think you could say that about any
20 one individual physician, that perhaps they don't
21 have authority from an organization to speak on
22 behalf of other physicians, but we -- you know,
23 we talk to each other constantly. We have
24 conferences constantly. We read the same medical
25 literature where there is papers, and there is

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1 letters to the editor, and there is editorials
2 and opinion pieces. We go to major meetings.
3 So there is a community of physicians that, you
4 know, largely know what other physicians think
5 about things.

6 Q. Is there a single body, group,
7 organization of any kind that has deputized or
8 authorized you to speak for any other physician
9 in this case?

10 A. No, I wouldn't say that.

11 Q. You understand that reasonable
12 physicians can have different opinions on any one
13 of a number of topics; right?

14 A. Yes, I understand that. There is
15 some extreme positions on either side of many
16 medical issues, but I think the bulk of
17 physicians are largely in agreement on most
18 things. But certainly there is a range of
19 opinions about various medical issues.

20 Q. What, if anything, have you done in
21 any formal way to determine what percentage of
22 physicians would agree with your opinions in this
23 case?

24 A. Well, I certainly haven't spoken to
25 any physicians specifically about IVC filters,

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1 thing to do. I think I am a pretty
2 middle-of-the-road, reasonable physician.
3 Presented with evidence I come to a conclusion,
4 so I think most physicians would come the same
5 conclusions as me. I understand that there is
6 extremes. I understand there is differences of
7 opinion, but on the whole I think we are pretty
8 reasonable, and we look at evidence pretty much
9 the same way.

10 Q. I think I understand. I think maybe
11 the problem is the word choice that I am using.
12 You can't say with any degree of certainty that
13 any given doctor would agree with your opinion,
14 although it is your belief based on your
15 education, experience and training that a
16 reasonable doctor would. Is that fair?

17 A. Yes.

18 Q. Could we go off the record?

19 BY THE VIDEOGRAPHER: Going off the
20 record at 10:39 a.m.

21 BY THE VIDEOGRAPHER: This begins
22 tape number two in the deposition of Dr. Mark
23 Eisenberg. We are back on the record at
24 10:50 a.m.
25

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1 A. Well, I certainly agree that it's
2 offered as ethics guidance. I -- you know, I
3 understand the simple meaning of the rest of the
4 sentence. I can't say as to whether that has
5 actually -- has been established as standards of
6 clinical practice or rules of law.

7 Q. I think that's fair. Let me try to
8 break that down into the two components. You
9 understand and appreciate that the document that
10 we have marked as Exhibit 8 referenced in
11 paragraph 24 provides ethical guidance?

12 A. Yes.

13 Q. As to whether or not it establishes
14 a standard of any kind or rule of law, you can't
15 answer one way or the other; right?

16 A. I think that most physicians would
17 understand that the recommendations by the
18 American Medical Association are pretty strong
19 ethics guidelines, and most physicians would
20 attempt to follow them. I don't know if that
21 answers your question.

22 Q. I think so. Let me try to rephrase
23 it. You think that most physicians would
24 understand that Exhibit 8 constitutes pretty
25 strong ethical guidelines that should be

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1 followed; right?

2 A. Yes.

3 Q. Whether or not Exhibit 8 is binding
4 in any legal sense, you would defer to others who
5 could discuss the binding impact, if any, on
6 Exhibit 8; right?

7 A. Yes, that's correct. I don't -- I
8 don't know exactly what the law says about
9 informed consent.

10 Q. Nor would you in any way purport to
11 give any legal opinions in this case, right?

12 A. I am familiar with some legal terms
13 and some legal procedures, but I certainly can't
14 hold myself out as any kind of expert in legal,
15 you know, procedures.

16 Q. Do any of the opinions you have in
17 this case have anything to do with legal
18 obligations of Bard?

19 A. Again, I don't think I can speak to
20 legal obligations. That's not my area. I have
21 opinions that I think are shared by most
22 physicians about what Bard should and should not
23 do and what kinds of information need to be given
24 to physicians, what kinds of information need to
25 be available to patients. But as to what's

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1 legally required, I can't speak to.

2 Q. Now, paragraph 25 also is from the
3 AMA Code of Medical Ethics; right?

4 A. Yes.

5 Q. So again it's an ethical guidance;
6 right?

7 A. It is ethical guidance. And I would
8 like to get back to the legal issue. Again, I
9 can't hold myself out as an expert in the legal
10 issues, but the my understanding that you -- it
11 would be wrong to, for example, do a procedure
12 without obtaining informed consent first from a
13 patient, except under unusual circumstances where
14 they can't respond, for example.

15 Q. With that -- strike that. With that
16 explanation in mind, are there any paragraphs in
17 your expert report here that touch on what you
18 consider to be Bard's violation of a legal duty?

19 A. No, I don't think I have any
20 paragraphs like that.

21 Q. Paragraph 25 quotes, as we have
22 established from the AMA code of medical ethics;
23 right?

24 A. Is that a question?

25 Q. Right. I am just establishing

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1 already out there for physicians to read, and I
2 think they were reading and responding to it. I
3 have other sections of my report where I discuss
4 that I think Bard should have done controlled
5 trials or certainly prospective studies to look
6 at the efficacy and safety of their devices. So
7 I think there is various parts of my report.
8 They don't all deal with, you know, the specific
9 point that you were making.

10 BY MR. BUSMAN:

11 Q. You leave regulatory testimony and
12 determinations up to the regulatory experts that
13 Plaintiffs have disclosed; right?

14 A. Yes, I leave the technical
15 considerations to the regulatory experts,
16 although I certainly read that and, in my context
17 of being a practising physician who implants
18 temporary and permanent devices, who has patients
19 that, you know, have filters, I think I can
20 respond to some of those issues.

21 Q. Your opinions are based on what you
22 believe a responsible, moral and ethical device
23 manufacturer would have disclosed to physicians.
24 Is that fair?

25 A. Yes, that's fair.

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1 although I think there is -- it's implicit in
2 these paragraphs, because these paragraphs
3 discuss how a physician obtains informed consent
4 before doing a procedure, and they have to be
5 able to disclose to the patients the risks,
6 complications and expected benefits of the
7 procedure or device to the patient. So in order
8 to be able to do that they have to know what the
9 risks, complications and benefits are and how
10 frequently they occur.

11 Q. I am going to object and move to
12 strike as non-responsive. Is there anything in
13 paragraph 26 where you quote from these practice
14 guidelines that specifically references any
15 binding duty, obligation or responsibility of a
16 medical device manufacturer?

17 MR. ROTMAN: Objection. Asked and
18 answered.

19 THE WITNESS: No, there is nothing
20 specifically, you know, identifying the
21 responsibility of a medical device company in
22 these paragraphs.

23 BY MR. BUSMAN:

24 Q. Is Exhibit 9, in your opinion, the
25 same type of document as Exhibit 8 in terms of

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1 risks and complications and benefits of a
2 particular device and, you know, in order to
3 deliver that information to a patient.

4 BY MR. BUSMAN:

5 Q. Let's take that in its component
6 parts. I am going to break it down, because you
7 said two separate things. You agree with me that
8 the documents cited in paragraphs 24, 25 and 26
9 do not constitute any legally binding authority,
10 requirement that Bard in a legal sense should
11 have complied with; right?

12 A. Yes, I think that's correct.

13 Q. It's your opinion; nonetheless, that
14 doctors, physicians would consider the documents
15 you have cited in paragraphs 24, 25, and 26 as
16 strong ethical guidance in terms of what a
17 physician is required to do to obtain informed
18 consent from his patient; right?

19 A. Yes. I would even go as far to say
20 those are probably authoritative documents in
21 terms of how you should go about obtaining
22 informed consent.

23 Q. Let's take a look at paragraph 27.
24 I will read it into the record.

25 "The totality of the evidence

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1 authority to speak for all other physicians.

2 Q. You suspect and hope that reasonable
3 physicians would agree with the opinions that you
4 have set forth in your report; right?

5 A. I think -- the words I would use
6 would be stronger than "suspect" and "hope". I
7 am confident that most physicians would be
8 comfortable with these opinions.

9 Q. Okay. It's your expectation that a
10 reasonable physician would agree with the
11 opinions that you express in your report when you
12 refer to what a reasonable physician would want
13 to know; right?

14 A. Right.

15 Q. You can't; however, say with any
16 degree of certainty what any individual physician
17 would want or wouldn't want. That specific
18 person would have to speak for themselves; right?

19 A. Yes, I think we went over this
20 before. There is the vast group of physicians
21 and then there is any one individual. You can't
22 say what that person is going to say.

23 Q. Let's turn to 29 and take a quick
24 look at that one. Are you there?

25 A. Yes.

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1 evidence demonstrating high
2 rate of complications with the
3 filters, Bard did not address
4 these issues in a way that
5 accurately and timely
6 disclosed or explained the
7 risks to physicians."

8 Did I read that correctly?

9 A. Yes, you did.

10 Q. Is it your opinion in this case that
11 Bard intentionally withheld information from
12 physicians?

13 A. I don't think I can speak to
14 intentions of individuals or companies. You
15 know, I am not an expert. I don't know if there
16 are experts in terms of interpreting intentions.
17 I am aware that there was data available to Bard
18 showing high rates of complications. It does not
19 look like these data were shared with physicians
20 but as to, you know, whether there was intention
21 or not, I can't speak to that.

22 Q. Is it your opinion that Bard
23 violated any obligation, responsibility,
24 regulation, law or duty with respect to the
25 conduct that you describe in paragraph 31?

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1 MR. ROTMAN: Objection. Complex
2 question. Do you want to break it down? That
3 would be fine.

4 BY MR. BUSMAN:

5 Q. Can you answer it the way I asked?

6 A. It would be better that you break it
7 down.

8 Q. What, if any, binding authority, in
9 your opinion, did Bard fail to comply with in
10 connection with the conduct described in
11 paragraph 31?

12 MR. ROTMAN: Objection.

13 THE WITNESS: So as we discussed
14 earlier, I am not an FDA expert or regulatory
15 expert, so I am not familiar with the FDA rules,
16 so I can't say whether they broke any rules by
17 not providing this information.

18 BY MR. BUSMAN:

19 Q. Are you claiming that Bard failed to
20 comply with any moral or ethical responsibility
21 in connection with the conduct outlined in
22 paragraph 31?

23 A. Again, I don't hold myself out to be
24 an expert in ethics, but as a reasonable
25 physician who, you know, implants permanent and

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1 temporary devices in patients and who routinely
2 gets informed consent from patients, I would feel
3 that there is a responsibility for the company to
4 let physicians know about complication rates.

5 Q. An ethical responsibility?

6 A. I guess you could say an ethical
7 responsibility. They may have a regulatory
8 responsibility as well, but I can't speak to
9 that.

10 Q. Let's take a look at 31. Let me
11 know when you have read that. I will read the
12 first sentence:

13 "Instead of exercising the
14 kind of transparency
15 physicians and patients expect
16 from a medical device company
17 like Bard, Bard continued to
18 represent these devices as new
19 and improved compared to
20 predicate and competitor
21 devices."

22 Did I read that correctly?

23 A. Yes, you did.

24 Q. You used the word "transparency".
25 Is it your opinion in paragraph 32 that Bard

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1 question again.

2 A. Okay.

3 Q. Is it your opinion in paragraph 32
4 that Bard intentionally withheld any information
5 about patient safety from physicians and
6 patients?

7 A. I am sorry. Can you repeat it one
8 more time, please?

9 Q. Read it back, please.

10 QUESTION WAS READ BACK.

11 THE WITNESS: So my response is
12 again, I can't speak to the company's intentions.
13 I would say it appears to me that that
14 information was withheld. That's all I have to
15 say.

16 BY MR. BUSMAN:

17 Q. Let me see if I can characterise
18 this once again at a broader level so we can kind
19 of move past some of these issues. Because as we
20 said, paragraph 32 follows a typical model for
21 various of the paragraphs in your report. Not
22 all of them but a lot of them; right?

23 A. Okay.

24 MR. ROTMAN: Objection.
25

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1 BY MR. BUSMAN:

2 Q. Would it be correct that you are
3 framing the record evidence in a way that you
4 believe would lead a reasonable person to infer
5 that information was intentionally withheld?

6 MR. ROTMAN: Objection.

7 THE WITNESS: I think it could be
8 inferred from the data that the information was
9 withheld from physicians and patients. You know,
10 I really can't speak to the intention of the
11 company, but it seems to me that they had data
12 available. It did not become available to
13 physicians and patients in a timely manner.

14 BY MR. BUSMAN:

15 Q. So would I be correct then in
16 stating that you have outlined the record
17 evidence and then are arguing that the evidence
18 appears to reflect that certain things were
19 withheld from FDA? That's your take-away based
20 on the evidence you have seen. Is that fair?

21 MR. ROTMAN: Objection.

22 THE WITNESS: Yes, and also -- and
23 beyond the FDA, the physicians and the patients
24 did not have access to this information in a
25 timely manner.

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1 about whether they want to buy that car or not.
2 So this is pretty much what's understood between
3 physicians and patients and a medical device
4 company, and consumers from any other kind of
5 company.

6 Q. Let's take a look a little further
7 on.

8 A. Could I add to that a little bit?
9 The opposite of transparency is a lack of
10 transparency. The lack of transparency was if
11 there was information available to the company
12 that these filters might not be functioning as
13 well as physicians and patients thought, and that
14 was not made apparent to the patients and the
15 physicians.

16 Q. Do you believe that Bard's lack of
17 transparency would be readily apparent to the
18 jurors if they were able to see the documents
19 that you saw?

20 A. Yes, I do. I think if the jurors
21 saw these documents they would say there is a
22 problem that physicians and patients were not
23 given this information in a timely manner.

24 Q. Let's take a look at paragraph 33.
25 Let me know when you are there. Are you at

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1 opinion in paragraph 33 comes from Bard's
2 internal documents; right?

3 A. It's partially from
4 Bard's internal documents, because there is
5 information in the internal documents about the,
6 you know, the complication rates associated with
7 the retrievable filters, but I also looked at
8 marketing materials that were sent to physicians,
9 that are publicly available documents as well.

10 Q. Did Bard, in your opinion, lie to
11 any doctors or physicians in connection with the
12 marketing materials that you reviewed?

13 A. I think that some of the marketing
14 materials that were given to physicians and also
15 instructions that were given, for example, to
16 representatives was misleading for physicians in
17 the sense that it led the physicians to believe
18 that the retrievable devices were just as safe
19 and efficacious as the predicate device, when in
20 fact they had internal information that that was
21 not the case.

22 Q. Would it be correct in saying it's
23 your opinion that Bard acted unethically in
24 connection with the marketing materials that you
25 are referencing?

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1 A. Again, I am not an expert on ethics.
2 I think that myself, as a physician, if I was
3 implanting these devices in patients and there
4 was information that this particular device did
5 not function as well as a competing device I
6 would be unhappy with the company, and if I knew
7 that information and I had a safer or more
8 efficacious alternative I would use that instead.

9 MR. ROTMAN: Off the record.

10 BY THE VIDEOGRAPHER: Going off the
11 record at 12:30 p.m.

12 BY THE VIDEOGRAPHER: This begins
13 tape number three in the deposition of Dr. Mark
14 Eisenberg. We are back on the record at
15 1:11 p.m.

16 BY MR. BUSMAN:

17 Q. Doctor, taking a look again at
18 paragraph 32, you refer to "lines of troubling
19 safety evidence". Do you see that?

20 A. Yes.

21 Q. Is "troubling" your word choice or
22 does that come from any document you read?

23 A. It's my word choice.

24 Q. Do you believe it was troubling to
25 Bard?

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1 A. I believe it was troubling to Bard
2 from reading their internal documents. They
3 created -- I forget the term exactly, but I think
4 it was a crisis management team. They used the
5 word "crisis". If I understand correctly, they
6 hired a public relations firm in case this
7 information became public, so I think "troubling"
8 is a good word.

9 Q. So would it be fair to say that you
10 are providing an opinion to a certain degree on
11 the state of mind of Bard when you used the word
12 "troubling"?

13 MR. ROTMAN: Objection.

14 THE WITNESS: Well, look, it's
15 troubling to me to see these complication rates
16 that I saw. You know, internally was the -- you
17 know, the adverse event data and also the in
18 vitro data, so I think that's troubling to me
19 that I was seeing those levels of complications,
20 but I think it was troubling to Bard as well,
21 based on their response to seeing these
22 complication rates.

23 BY MR. BUSMAN:

24 Q. By using the word "troubling", are
25 you in any way touching on Bard's intent or state

1 of mind?

2 MR. ROTMAN: Objection.

3 THE WITNESS: You know, I forget
4 what the word is, but we are attributing the
5 characteristics of an individual to a company
6 here. The word "troubling" is for an individual,
7 and you can't attribute that adjective to a
8 company. But there is no question that they were
9 following the data very closely. When they saw
10 that there were high complication rates they
11 reacted. So it was reactive, so I would call
12 that troubling. They saw it and they acted on
13 it.

14 BY MR. BUSMAN:

15 Q. Would you agree that you cannot give
16 any opinions that touch on anybody's intent, or
17 state of mind or motive, or would you disagree
18 with that?

19 MR. ROTMAN: Objection.

20 THE WITNESS: I think that I
21 certainly cannot do that. I think potentially
22 there might be some type of expert about it, who
23 could speak to intent, perhaps like a
24 psychiatrist, but myself, no. I can say: Okay,
25 there was data available. It either was or was

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1 Q. You are not an expert in corporate
2 compliance issues; right?

3 A. Again, I am not an expert in -- as a
4 regulatory expert or corporate compliance, but I
5 know what a reasonable physician, even what a
6 reasonable patient or someone in my family would
7 expect from a responsible company.

8 Q. Let me try one more time. Have you
9 identified in any expert report that you have
10 served any binding rule, regulation, standard,
11 guidance or document of any type which would be
12 binding on Bard that you believe Bard violated?

13 MR. ROTMAN: Objection.

14 THE WITNESS: I don't think I have
15 referenced any standard like that.

16 BY MR. BUSMAN:

17 Q. Let's go a little bit further into
18 -- skip ahead. Back to paragraph 33. If you
19 look one, two, three lines down, going in the
20 next line you refer to substantial improvements.
21 Do you see that?

22 A. Yes.

23 Q. Is that a term of art of some type?

24 A. I am sorry?

25 Q. Is the term "substantial

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1 need to be explored by larger prospective
2 studies.

3 Q. Move to object and strike as
4 non-responsive. Doctor, is it your opinion that
5 a responsible, ethical company in Bard's position
6 would have conducted prospective large,
7 well-controlled safety studies? Is that your
8 opinion?

9 A. I think that they needed to do them.
10 I think it was actually -- it was their intention
11 to do one with Recovery, if I am not mistaken, a
12 European study that for some reason never got
13 done. As to whether the FDA required those
14 studies or not, I can't speak to that. I can say
15 that physicians would want to see those studies.

16 Q. Do you believe that Bard had some
17 type of responsibility to do those studies?

18 A. I do.

19 Q. Do you believe that Bard had an
20 ethical responsibility to do those studies?

21 MR. ROTMAN: Objection.

22 THE WITNESS: I think that they had
23 an ethical responsibility to do those studies in
24 view of the data that they had from their small
25 retrievability studies.

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1 requirement with respect to the conduct outlined
2 in paragraphs 34, 35 and 36?

3 A. So I am not an FDA regulatory
4 expert, so as to whether or not they complied
5 with the FDA regulations, I can't speak to that.

6 Q. To the extent you take issue with
7 the conduct we are discussing in paragraphs 34 to
8 36, would it be fair to say that it's your
9 opinion that a reasonable, ethical and moral
10 company would have conducted the studies that you
11 have discussed?

12 A. I think that's correct. I think a
13 reasonable physician would want that information.
14 For sure patients and their families would want
15 that kind of safety information, which was not
16 available.

17 Q. Take a look at 37, please. Let me
18 know when you have read it.

19 A. Okay.

20 Q. I am going to read the last
21 sentence:

22 "As a physician with patients
23 who are candidates for IVC
24 filters or have them
25 implanted, I would expect that

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1 have been marketed based on
2 the in vitro test results."

3 Are you giving a regulatory opinion
4 there? Yes or no?

5 A. Maybe we should say I am not giving
6 a regulatory opinion, because I am not an FDA
7 regulator. But as a physician, and I use the
8 word "I", I would expect that that's evidence
9 that the filters are not substantially
10 equivalent.

11 Q. It's your personal opinion?

12 A. Personal opinion, and also opinion
13 that I think would be shared by the vast majority
14 of reasonable physicians and certainly patients
15 as well.

16 Q. Okay. I am going to move quickly
17 here. Paragraph 38, you are just doing a
18 narrative here of what you believe the facts are;
19 right?

20 A. Yes.

21 Q. Okay. What documents have you
22 relied on to support your opinions in paragraph
23 39?

24 A. So there is a spreadsheet. A Bard
25 internal document has a spreadsheet that shows

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1 Q. Would you -- strike that. Would it
2 be your opinion in this case that these documents
3 that you have cited are generally accepted
4 ethical standards for responsible companies?

5 A. Yes, I think that's the case. I
6 think that I should add -- part of the reason I
7 included it is because it's discussing at page
8 five of this document, it discusses
9 characteristics of a good case report and, on
10 page six, developing a case series, indicating
11 that the FDA thinks that these types of data are
12 -- are adequate signals that there may be a
13 problem with a drug or a device.

14 Q. Let's try to break this down a bit.
15 It's not your opinion that any of these documents
16 we have gone over today constitute any legally
17 enforcing or binding authority on Bard; right?

18 A. No, that's correct.

19 Q. You do; however, believe that
20 reasonable physicians and a reasonable
21 manufacturer would look to any of these documents
22 for strong ethical guidance to guide their
23 conduct; right?

24 A. Yes, and I would say patients and
25 their families would look to that, specifically

1 with respect to patient safety.

2 Q. Let me rephrase that to get that in
3 there; okay? You believe that the various
4 guidance documents that we have discussed, all of
5 the guidance documents you have referenced in
6 your expert report in this case constitute strong
7 ethical guidelines that reasonable physicians and
8 patients would expect a device manufacturer to
9 comply with; right?

10 MR. ROTMAN: Objection.

11 THE WITNESS: Yes, I think that's
12 right.

13 BY MR. BUSMAN:

14 Q. Would you say that essentially the
15 gist of what we are talking about here, to boil
16 it down, is the company should bear
17 responsibility for their products? Is that the
18 point you are trying to make here?

19 MR. ROTMAN: Objection.

20 THE WITNESS: I think that's one of
21 the many points that I am trying to make.

22 BY MR. BUSMAN:

23 Q. Right. I didn't mean to suggest
24 that you don't have other points. Let the record
25 be perfectly clear. You make numerous other

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1 points. Would it be fair to say that one of the
2 primary drivers of your opinions in this case,
3 not exclusive, but one of the primary drivers is
4 that companies should bear responsibility for
5 their products; correct?

6 A. That's correct. I think that's
7 correct.

8 BY THE VIDEOGRAPHER: Going off the
9 record at 2:11 p.m.

10 BY THE VIDEOGRAPHER: Going back on
11 the record at 2:22 p.m.

12 BY MR. BUSMAN:

13 Q. Doctor, before we took a break we
14 were characterizing the standards that you have
15 cited in your expert report, and you agreed with
16 me that one of the drivers behind your opinion is
17 the notion that companies should bear a
18 responsibility for their products; right? That's
19 not controversial at all; right?

20 A. No.

21 Q. Bard or another device manufacturer
22 needs to be honest about the risks and hazards
23 associated with its products; right?

24 A. Yes, I agree with that.

25 Q. That's not controversial at all;

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1 right?

2 A. No, I don't think so.

3 Q. And that's one of the drivers,
4 again, of your opinions; right?

5 A. Yes.

6 Q. Take a look at 44. That's another
7 one of the narrative paragraphs; right?

8 A. Yes. Well, I mean -- go ahead. Why
9 don't you say what you want to say.

10 Q. When I say "narrative paragraph",
11 you understand that there are certain paragraphs
12 in your report that provide, I guess for lack of
13 a better word, the evidence as you see it, and
14 some contain your analysis and some contain both;
15 right? Is that a fair characterization of the
16 way the paragraphs are set up?

17 A. Yes. I am not sure it's so black
18 and white. We also have, you know, I have
19 paragraphs that I think evaluate evidence. I
20 think I have other paragraphs that evaluate the
21 temporal nature of what went on. There are
22 others putting the issues in context, I guess I
23 would say. I think this is one of those
24 paragraphs.

25 Q. Okay. You are making a point in

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1 Do you want to repeat the question?

2 Q. Sure. You are not saying anything
3 in paragraph 45 that you wouldn't expect Mr.
4 Williamson to say himself if he were called to
5 testify; right?

6 A. No, I think I quoted him extensively
7 in this paragraph.

8 Q. There is none of your analysis or
9 editorialising in this paragraph; right?

10 MR. ROTMAN: Objection.

11 THE WITNESS: Well, I state in a
12 couple of places, I say he agreed with a
13 statement because he stated it. So I don't know
14 if you call that interpretation on my part.

15 BY MR. BUSMAN:

16 Q. I guess my question is simpler.
17 Paragraph 45 is one of the paragraphs where you
18 simply recount what the record evidence is as you
19 see it with respect to this particular issue?

20 A. Yes, that's correct.

21 Q. You are not expressing any one of
22 your actual opinions in paragraph 45. Rather you
23 are setting forth some record evidence; right?

24 A. Yes.

25 Q. Let's turn to 46. You don't hold

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1 yourself out as an expert in corporate compliance
2 with corporate standards; right?

3 A. No, I can't say that I am an expert
4 in that area.

5 Q. Take a look at 47. Let me know when
6 you have had a chance to read it.

7 A. Okay.

8 Q. 47 is another narrative paragraph
9 where you are simply setting forth the record
10 evidence; right?

11 A. That's correct.

12 Q. You are not an expert on Bard's
13 standard operating procedures, are you?

14 A. I am not an expert on corporate
15 operating procedures, although I would say that I
16 understand the importance of their standards. I
17 think it's, you know, they are necessary for
18 patient safety that such standards be in place
19 and that the -- that the company has these
20 standards, that they should adhere to them.

21 Q. Take a look at 48, please, and let
22 me know when you have read it.

23 A. Yes.

24 Q. 48 is another one of the narrative
25 paragraphs where you simply recount the record

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1 a forum for discussion, patient safety and, you
2 know, the efficacy and safety of medical devices
3 and drugs.

4 Q. All right. Let's go through some of
5 these. We can go through pretty quickly. Take a
6 look at 57, please. That's one of the narrative
7 paragraphs; right?

8 A. Well, it's largely narrative, but it
9 also discusses, as I mentioned earlier, this
10 multicentre study about the SNF, you know,
11 attesting to its safety. And the tail end of
12 that paragraph is, you know, comparing failure
13 rates, the SNF versus the retrievable filters.

14 Q. You are not stating anything in
15 paragraph 57 that's not contained in some type of
16 a written document; right? That's what I am
17 asking.

18 A. No, none of this is my opinion.

19 Q. Okay. Let's take a look at 58.

20 Now, in the second sentence you said:

21 "Bard perceived a market
22 expansion opportunity to
23 develop retrievable IVC
24 filters."

25 Right?

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1 market niche for a retrievable filter, so they
2 said: We are going to take our successful SNF
3 and we are modify the design in order to make it
4 retrievable. But in order to modify the design
5 to make it retrievable the subsequent design, by
6 its very nature, was less resistant to migration,
7 and less resistant to fracture and less resistant
8 to tilt and embolization, and I don't think that
9 it was their intent to create such a device, but
10 what happened when they redesigned it not to make
11 it retrievable, it became a less vigorous filter.

12 Q. You are not an expert in filter
13 design; right?

14 A. I am not an expert in filter design.

15 Q. Let's take a look, if you will,
16 please, at paragraph 59. 59 is a narrative
17 paragraph; right?

18 A. Yes.

19 Q. Paragraph 60 is also a narrative
20 paragraph; right?

21 A. Yes, that's correct.

22 Q. 61 is another narrative paragraph,
23 right?

24 A. I agree that these are all narrative
25 paragraphs, but I think that they are sort of

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1 important to understand that -- you know, the
2 temporal nature of what was going on here and the
3 environment.

4 Q. Take a look at 62. That's another
5 narrative paragraph, meaning it doesn't contain
6 any actual opinion that you have. You are just
7 recounting the factual record as you see it;
8 right?

9 MR. ROTMAN: Objection.

10 THE WITNESS: Well, except for the
11 last line where I say:

12 "At no time did Bard ever show
13 that the Recovery had similar
14 performance characteristics to
15 the SNF."

16 So I would say that's a
17 non-narrative statement.

18 BY MR. BUSMAN:

19 Q. You haven't reviewed the entire
20 documentary record in this case; right?

21 A. I am not sure what you mean by that.

22 Q. You haven't reviewed every single
23 page of every document that Bard has produced in
24 this litigation; right?

25 MR. ROTMAN: Objection.

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1 context, as I mentioned earlier there was three
2 major lines of evidence I was evaluating here. So
3 one line was the medical literature, and one line
4 was the in vitro testing and one line was the
5 adverse events data. So the adverse events data
6 was being tracked closely by Bard and, when they
7 saw unexpected complications, they called in Dr.
8 Lehmann to confirm it, which he did. And then,
9 you know, the Attorneys asked Dr. Betensky to do
10 an independent analysis of the same Bard data,
11 and she came to the, you know, I think, to the
12 same conclusions which were there are elevated
13 complication rates.

14 Q. I am going to object and move to
15 trying as non-responsive. In the section of your
16 report heading E: "Betensky Analyses, Adverse
17 Events", you don't say anything in any of these
18 paragraphs about Dr. Betensky's report that isn't
19 already contained in her own report; right?

20 MR. ROTMAN: Objection. Advise that
21 the Witness review the paragraph before answering
22 the question, unless you know from memory.

23 THE WITNESS: Yes, I think the
24 section on Dr. Betensky's analyses largely
25 recapitulates the results of her analyses, and I

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1 don't extend them beyond what she has said.

2 BY MR. BUSMAN:

3 Q. Have you reviewed any of Dr.
4 Betensky's other expert reports, like her
5 rebuttal report to Dr. Feigal or Dr. Fiska?

6 A. What I have reviewed was her expert
7 report, plus she had an addendum. Those are the
8 two reports from her that I examined. A
9 supplement. A supplement.

10 Q. Okay. Let me hand you what we will
11 mark as Exhibit 12. It is Dr. Betensky's
12 rebuttal to the expert report of Dr. Feigal. You
13 haven't seen this before, have you?

14 A. Let me take a look.

15 Exhibit 12 was marked for
16 identification.

17 BY MR. BUSMAN:

18 Q. In particular, while you are taking
19 a look at this why don't we go off the record
20 and, while we are off the record, we can take a
21 break and you can, please, if you will, read
22 paragraph one in its entirety, which goes from
23 the first page on to the second page.

24 A. Okay.

25 BY THE VIDEOGRAPHER: Going off the

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1 another, because it might be outside of the focus
2 of an epidemiology study that you --

3 A. But I completely understand what she
4 did, and I understand what it means.

5 MR. ROTMAN: I object to the
6 question.

7 BY MR. BUSMAN:

8 Q. If you could turn to heading H,
9 "Discussion of the Medical Literature". Take a
10 look at paragraph --

11 A. What paragraph?

12 Q. I am talking about paragraph 137,
13 but in general we have moved to your discussion
14 of the literature. Take a look at paragraph 137.
15 It states:

16 "The adverse event rates
17 reported in this study are
18 extremely high and would have
19 dissuaded most physicians from
20 using this device if it had
21 still been on the market."

22 Did I read that correctly?

23 A. Yes.

24 Q. You can't say to any degree of
25 certainty what any given physician would have

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1 done with this information. You are speculating
2 that most physicians would not have used the
3 device; right?

4 A. The statement is on the basis of
5 what I recognize as necessary for patient safety
6 and that I think other physicians would recognize
7 as necessary for patient safety. So high event
8 rates in a particular device are going to make
9 the physician step back and say: I don't want to
10 use that device.

11 Q. You might be right and you might be
12 wrong, but it calls for speculation for you to
13 say what most physicians would have done with
14 this information; right?

15 A. Again, I would say I think in the
16 issue of patient safety, I think that most
17 physicians would be in pretty uniform agreement.

18 Q. Would you characterize that as an
19 educated guess?

20 A. No, I think that -- we are all
21 trained the same way, to be very risk averse.
22 Patients are obviously risk averse as well. So
23 if we see a report in the literature that has a
24 high risk associated with a device, we -- you
25 know, rightly or wrongly we step back and say: I